



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0116; FRL-9412-16-OCSPP]

### **Certain New Chemicals or Significant New Uses; Statements of Findings for May, June, and July 2022**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Toxic Substances Control Act (TSCA) requires EPA to publish in the *Federal Register* a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from May 1, 2022 to July 31, 2022.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0116, is available online at <https://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics,

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*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this action apply to me?*

This action provides information that is directed to the public in general.

#### *B. What action is the Agency taking?*

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the reporting period.

#### *C. What is the Agency's authority for taking this action?*

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make one of the following specific findings:

- The chemical substance or significant new use presents an unreasonable risk of injury to health or the environment;
- The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use;
- The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects and the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment;

- The chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance; or
- The chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment.

Under TSCA, the unreasonable risk findings must be made without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant under the conditions of use. The term “conditions of use” is defined in TSCA section 3 to mean “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

TSCA section 5(g) requires EPA to publish in the *Federal Register* a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of “not likely to present an unreasonable risk of injury to health or the environment” may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

## **II. Statements of Findings under TSCA Section 5(a)(3)(C)**

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

The following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as CBI).

- J-22-0012, J-22-0013, Genetically modified microorganism for the production of a chemical substance (Generic Name).

To access EPA's decision document describing the basis of the "not likely to present an unreasonable risk" finding made by EPA under TSCA section 5(a)(3)(C), look up the specific case number at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely>.

**Authority:** 15 U.S.C. 2601 *et seq.*

Dated: August 15, 2022.

**Madison Le,**

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*Office of Pollution Prevention and Toxics.*

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